

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-md-2738-
FLW-LHG**

MDL No. 2738

THIS DOCUMENT RELATES TO ALL CASES

**PLAINTIFFS' STEERING COMMITTEE'S REPLY MEMORANDUM OF
LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS
AND TESTIMONY OF PERSONAL CARE PRODUCTS COUNCIL'S
EXPERT JONATHAN BORAK, M.D., DABT**

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this reply to *Defendant Personal Care Products Council's Opposition to Plaintiffs' Motion to Exclude the Opinions of Jonathan Borak, M.D., DABT* (ECF No. 9887) ("PCPC Opp.") and in further support of *The Plaintiffs' Steering Committee's Memorandum of Law in Support of Its Motion to Exclude the Opinions of Defendants' Epidemiology Experts* (ECF No. 9737-1) ("PSC Brief").¹

I. INTRODUCTION

Defendant Personal Care Products Council ("PCPC") claims Dr. Jonathan Borak's expert opinion satisfies Rule 702 of the Federal Rules of Evidence because his opinion "is based on sufficient facts or data" and is "the product of reliable principles and methods." However, for the foregoing reasons, Dr. Borak's report and his opinions contained therein are deficient on both counts and should be excluded.

¹ The PSC Brief (and related motion) moved to exclude the opinions of all the epidemiologists offered by the Johnson & Johnson Defendants ("J&J") and PCPC. This reply pertains solely to the PCPC Opp. The PSC is filing a separate reply brief contemporaneously with the filing of this reply brief to further support the motion as it pertains to the epidemiology experts offered by the J&J defendants.

II. ARGUMENT

A. DR. BORAK DID NOT APPLY AN ACCEPTABLE METHODOLOGY TO REACH HIS CONCLUSIONS

In his expert report Dr. Borak concludes that “science has not established that perineal talc use causes ovarian cancer.”² In support of that conclusion Dr. Borak provides a chronological summary of studies related to talcum powder and ovarian cancer.³ This summary is devoid of data and, more importantly, absent any independent analysis of the data that underlies each study. Dr. Borak’s report purported to “analyze the above materials from a chronological perspective in order to evaluate whether, when and by whom it had been determined that perineal use of talc-containing powder causes ovarian cancer.”⁴ Important to this PSC motion, Dr Borak’s mandate was not to make an independent determination of causation, but rather to prepare a chronology of what others had determined.

PCPC claims that none of the PSC’s experts “exceed[ed] the number and breadth of materials” Dr. Borak reviewed, and that he used his “45 years of experience and training to evaluate the merits” of those materials.⁵ This is PCPC’s best effort at casting Dr. Borak’s methodology as generally accepted. PCPC draws

² Borak Report at 3, 13.

³ *Id.* at 3-13.

⁴ *Id.* at ¶ 8.

⁵ PCPC Opp. at 9-10.

upon nothing else to support that claim. In preparing an expert report and rendering an expert opinion pursuant to Rule 26 of the Federal Rules of Civil Procedure, the issue is not simply one of the *quantity* of material allegedly reviewed, but of the *quality* of the review along with the methodology utilized in the review. It is here that Dr. Borak comes up short.

Dr. Borak's report reflects that he failed to apply even the most rudimentary methodology to analyze his self-selected data. Further, Dr. Borak admitted in his deposition testimony that he did not even *attempt* to answer the question of whether talcum powder can cause ovarian cancer.⁶ The PSC has already documented at length Dr. Borak's failure to employ a Bradford Hill analysis or indeed any other generally accepted causation methodology to reach his conclusions.⁷ As evidenced by its response to the PSC Brief, PCPC cannot dispute this fundamental flaw in how Dr. Borak reached his conclusions and expressed them in his report. In the PCPC Opp., PCPC itself is unable to articulate a generally accepted methodology used by Dr. Borak in reaching his conclusions. In fact, although PCPC devotes nearly ten pages trying to answer the PSC's arguments on Dr. Borak's lack of methodology, most of those ten pages are actually spent attacking the PSC's experts. This presents as an attempt to distract from Dr. Borak's own obvious methodological

⁶ See PSC Brief at 62, *citing* to Borak Report at 1-13.

⁷ See PSC Brief at 63-65.

inadequacies. In the end, PCPC's responsive argument in support of the acceptability of Dr. Borak's opinions is that he was well compensated for his review of a lot of documents and he has been a doctor for a long time.

In fact, throughout his deposition, Dr. Borak *repeatedly* admitted he was not asked to comment on causation in his report, nor did he set out to do so. Dr. Borak expressly admitted he did not conduct a Bradford Hill analysis.⁸ Dr. Borak expressly admitted he did not offer an opinion on the hierarchy of evidence.⁹ Dr. Borak expressly admitted he was not even asked to opine on causation, and consequently did not perform any analysis that would enable him to reach a conclusion on that issue.¹⁰ Setting aside that Dr. Borak's lack of methodology would render any such opinion of his inherently unreliable, it is also impossible for Dr. Borak to offer an opinion on that issue *because he was never asked to do so and did not try*.

PCPC asserts that Dr. Borak is qualified to "opine[] that science has not established that perineal talc use causes ovarian cancer."¹¹ In so doing, PCPC offers Dr. Borak's list of references and credentials and asks this Court to find that he is qualified to render a causation opinion on those bases alone. However, having

⁸ Borak Dep. at 103:3-21; 113:21-115:14; 160:11-161:8; 196:8-197:21; 221:23-222:23.

⁹ *Id.* at 219:2-221:22; 271:19-272:16.

¹⁰ *Id.* at 115:9-14; 342:5-6.

¹¹ PCPC Opp. at 7.

credentials in certain fields is not sufficient by itself to establish that the expert utilized a recognized and reliable methodology for establishing causation. If that were so then the PSC would have challenged Dr. Borak's qualifications.¹² Instead, the scientist must demonstrate that he/she utilized a recognized and reliable methodology. Mere experience does not necessarily equate to analyzing an issue in a scientifically sound manner. Dr. Borak's qualifications as a toxicologist and internist are not at issue here. What is at issue is that he is not an epidemiologist, and he did not perform a causation analysis utilizing a recognized and reliable methodology.

PCPC cites two cases to support the proposition that "reviewing the relevant literature and drawing on their experience" is a generally accepted methodology for an epidemiologist to render a causation opinion. Upon examination, both cases offered are non-binding authority that are completely inapposite and provide no support for PCPC's argument. First, *In re Yasmin & YAZ (Drospirenone) Mktg.*,

¹² This point is especially relevant given Dr. Borak's particularly superficial credentials as an epidemiologist. Dr. Borak is clearly an experienced toxicologist and internist. PCPC notes he is board certified in both disciplines and maintains membership in numerous professional associations that relate to those specialties. To that end, Dr. Borak may very well be qualified to render an expert opinion in the fields of toxicology and internal medicine; however, none of his credentials are remotely close to designating him an expert in epidemiology. Dr. Borak's education, experience, and published works refute the notion that he is an expert in the field with appropriate foundational experience and methodology to satisfy *Daubert*.

Sales Practices & Prod. Liab. Litig., No. 3:09-md-02100-DRH, 2011 WL 6302573 (S.D. Ill. Dec. 16, 2011), is immediately distinguishable because the challenged expert *actually applied a methodology*. The expert, Dr. Stephen Hulley, was a board-certified epidemiologist who chaired a university department of epidemiology. Defendants challenged Dr. Hulley on, *inter alia*, the issue of whether he improperly considered the respective quality of journals as a *factor* in his methodology, which the Court deemed was permissible based on his extensive experience as an author in the field. While Dr. Hulley certainly drew on his experience and the relevant literature (much of which he authored, something Dr. Borak cannot say) to reach a conclusion as to whether the drug Yasmin caused an increased risk of venous thromboembolic (“VTE”) disease, he also “summarized and individually critiqued the studies [and] combined the evidence in a meta-analysis.”¹³ In contrast, Dr. Borak conducted no such analysis here, nor has he authored an extensive body of published literature regarding the association between talcum powder and ovarian cancer.

The second case, *United States v. Caputo*, 374 F. Supp. 2d 632 (N.D. Ill. 2005), is even more far afield, as it did not implicate questions of causation or epidemiology at all. *Caputo* simply stated that an expert in toxicology was qualified

¹³ *In re Yasmin* 2011 WL 6302573 at *14.

to testify about what information regarding the risks of a sterilizer were commonly known among the scientific community at a given time.¹⁴

Dr. Borak may very well have undertaken a review of the thousands of pages he references in the various appendices of his report. Indeed there is no reason to doubt he has worked as a practicing physician for over four decades. However his claimed expert qualifications in the field of epidemiology appeared at best as tenuous and unsubstantiated upon examination. As a result, the bottom line is that Dr. Borak's report provides no nexus whatsoever between either the substance of those materials, his experience as a practitioner, and the ultimate causation opinion he renders in his report. Dr. Borak's report provides no analysis, no explanation of ways he weighed the evidence, no description of the strengths and weaknesses of studies, but rather concludes with the bald statement that "science has not established that perineal talc use causes ovarian cancer."¹⁵ This sort of fracture in reasoning is unsurprising considering Dr. Borak's testimony that he did not even set out to prove or disprove causation. Dr. Borak admitted he "didn't touch" any of the underlying data supporting those conclusions.¹⁶ Dr. Borak's total disregard of the data reported in the studies upon which he supposedly relies is an indictment of his (non-existent)

¹⁴ *Caputo*, 374 F. Supp. 2d at 641-42.

¹⁵ Borak Report at 12.

¹⁶ Borak Dep. at 294:20-21.

methodology and proof that his conclusions are not supported by “sufficient facts or data.” Dr. Borak could have referenced a million pages of documents; his decision to arbitrarily ignore the underlying data renders his opinion bereft of the facts or data necessary to support reliability.

B. DR. BORAK DISAVOWED ANY OPINIONS THAT HAD BEEN SET OUT IN HIS REPORT

As highlighted in the PSC Brief at 62-64, to the extent Dr. Borak offered an opinion in his report that “science has not established that perineal talc use causes ovarian cancer,” he disavowed any such opinion at his deposition. As he testified at his deposition, Dr. Borak is not providing an opinion on whether or not talcum powder can cause ovarian cancer:

Q. And just to be clear, in this case that brings us here today, you did not do a Bradford Hill analysis, correct?

A. Yes, I did not do a Bradford Hill analysis.

Q. And you were not asked to do a Bradford Hill analysis?

A. That’s correct.

Q. --- While you commented on, my words, the state of the science, you were not asked **nor did you give an opinion on whether or not talc can cause ovarian cancer?**

A. **I did not – I was not asked to render such an opinion.**¹⁷

¹⁷ *Id.* at 103:3-21.

Having clearly stated at deposition that he was not giving an opinion on whether or not talc can cause ovarian cancer, PCPC is unable to argue the contrary and unsubstantiated conclusion in Dr. Borak's report that "science has not established that perineal talc use causes ovarian cancer" should be admitted. Dr. Borak has disavowed that opinion and it can no longer be offered for purposes of general causation.

III. CONCLUSION

For the foregoing reasons, Dr. Borak's report lacks both the methodology and factual basis necessary to render a reliable opinion on causation pursuant to Fed. R. Evid. 702, and this Court should grant the PSC's Motion to Exclude his opinion.

Respectfully submitted,

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